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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Southwest Region

Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
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November 17, 2004

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Charles H. Rose
CEO
Nuclear Cardio Systems, Inc.
5660 Airport Boulevard, Suite 101
Boulder, CO 80301

Ref # DEN-05-02

Dear Mr. Rose:

During an inspection of your establishment located in Boulder, Colorado on July 8 – 16, 2004, investigators from the U.S. Food and Drug Administration (FDA) determined that your firm manufactures and remanufactures emission computed tomography systems. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(h)].

As discussed with you at the close of the inspection, and described in the Form FDA-483 left with you, the investigators found evidence that your medical devices are adulterated under Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformance with Current Good Manufacturing Practice (CGMP) requirements. CGMP requirements are set forth in FDA's Quality System (QS) regulation, Title 21, Code of Federal Regulations, Part 820 [21 CFR 820]. Significant deviations include, but are not limited to, the following:

1. Failure to establish and maintain device master records (DMR) for your manufactured and remanufactured emission computed tomography systems [21 CFR 820.181]. Specifically, for the:

    a. RS 7500, remanufactured 75 PMT Spect Imaging System;
    b. CardioSpect D90, fixed 90 dual headed Spect Imaging System;
    c. CardioSpect SC, single head circular field of view Spect Imaging System and;
    d. NeuroSpect QUAD, fixed four headed Spect Imaging System.

The DMR for each device must include, or refer to the location of: the device specifications; production process specifications; quality assurance procedures and specifications; packaging and labeling specifications; and installation, maintenance, and servicing procedures and methods [21 CFR 820.181(a) thru (e)].

2. Failure to establish and maintain procedures to control the design of your devices in order to ensure that specified design requirements are met [21 CFR 820.30(a)]. Your CardioSpect D90, CardioSpect SC, and NeuroSpect Quad imaging systems were designed and developed for you by another firm; however, you do not have a design procedure or design plan for these devices which address the following: design development and planning, design input, design output, design review, design verification, design validation, design changes and their approval [21 CFR 820.30(b) thru (i)].

3. Failure to establish and maintain a procedure to control all required documents [21 CFR 820.40]. Our investigators noted that forms, manuals and procedures, including your Adverse Event Report form, CardioSpect D90 Acquisition Operator's Manual, revision X and Gamma Camera Daily Operational Quality Control Program were issued for use without documented review and approval [21 CFR 820.40(a)].

4. Failure to establish and maintain procedures for implementing corrective and preventive actions [21 CFR 820.100]. You must have procedures for analyzing processes, records, returned product and other sources of quality data to identify existing and potential causes of nonconforming product. Your procedures must also include: requirements for investigating nonconformities; identifying the actions needed to correct and prevent recurrence; verifying or validating the corrective and preventive action; implementing and recording methods and procedures changes; trending data; and dissemination of the information to management and individuals responsible for assuring quality of the product [21 CFR 820.100(a)(1) thru (7)].

5. Failure to establish and maintain procedures for finished device acceptance to ensure that each device meets acceptance criteria prior to release [21 CFR 820.80(d)]. Specifically, your firm does not have a written procedure for the on-site testing and acceptance of the CardioSpect D90, CardioSpect SC, and NeuroSpect Quad imaging systems which are manufactured and shipped for you by another firm.

6. Failure to establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system [21 CFR 820.22].

7. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit [21 CFR 820.198(a)]. The procedures must include an evaluation to determine whether the complaint represents an event which is required to be reported to FDA under 21 CFR 803, Medical Device Reporting [21 CFR 820.198(a)(3)].

   In addition, our investigators reviewed X of your firm's service reports. X of these reports appeared to meet the definition of a complaint [21 CFR 820.3(b)]; however, none

of these were considered by you to be complaints and were not included in your complaint file. In a discussion with our investigators, you asserted that "expected failures" and "field problems" did not qualify as complaints. The definition of a complaint, as stated in 21 CFR 820.3(b) is: "...any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution."

Since our investigators did not review all of your service records, and since you had no complaints in your complaint file, you should conduct a retrospective review of your service reports for complaints (including the nine pointed out to you) that should be reviewed, evaluated, and if necessary, investigated.

8. Failure of management with executive responsibility to establish, implement and maintain a quality policy at all levels of the organization [21 CFR 820.20(a)]. You have not established a quality plan, and you have not established a management review procedure or conducted management reviews of the quality system [21 CFR 820.20(c) and (d)].

We acknowledge receipt of your letter dated July 19, 2004, which responded to our form FDA-483. Your response is inadequate in that it does not contain specific steps you have taken or plan to take to address the conditions noted.

Our letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Act and regulations. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. These actions include seizure, injunction and/or civil penalties.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to: Food and Drug Administration, Denver District, P. O. Box 25087, Denver, CO 80225-0087, Attention: William H. Sherer, Compliance Officer. If you have any questions, please contact Mr. Sherer at (303) 236-3051.

Sincerely,

Susan J. Miller for

B. Belinda Collins
District Director